

REMARKS

I. Inquiry regarding status of Supplemental IDS

On June 9, 2003, Applicant filed a Supplemental Information Disclosure Statement citing U.S. Patent Number 6,531,461. Applicant respectfully requests that Examiner return an initialed copy of the Form 1449 form that was submitted therewith, indicating that the reference has been considered. Alternatively, if Examiner has not received the Supplemental IDS, Applicant requests notification of this fact so that Applicant may re-submit the supplemental IDS (with proof of the original submission date).

II. Status of the claims and support for the amendment

Claims 2, 9, and 14-23 are cancelled herein.

Claims 1, 3-6, 8, 10, 11, and 13 are currently amended.

Claims 1, 3-8, and 12-13 are pending.

Support for the amendments to the claims is found in the claims as originally filed and at pages 3, 4 and 6-8 of the Specification.

III. Rejection under 35 U.S.C. §112

Claims 2-6 and 9-13 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Specifically, the rejection alleges that:

claims 2-6 and 9-13 are rendered vague and indefinite because they are outside the limitations of independent claims 1 and 8, from which they depend—i.e., claims 1 and 8 define an anti-neoplastic pharmaceutical composition (and method of preparing) which is obtained from *Vernonia amygdalina* leaves via the steps recited in claims 1 and 8 (via extracting with water then collecting the filtrate thereof) which represents a filtered crude water extract thereof. However, claims 2-6 and 9-13 are drawn to anti-neoplastic compositions...defined by various fractions and subfractions of filtered crude water extract (i.e. obtained from the antineoplastic crude water filtrate of claims 1 and 8 via one or more chromatographic steps) and not to the actual filtered crude water extract or method defined by claims 1 and 8. Accordingly, claims 1 and 8 are rendered vague, indefinite, and confusing as they do not define the defined product (or

method) of claims 1 and 8....It is also unclear by the steps recited in claims 2-6 and 9-13...as to what constitutes the final pharmaceutical product—which also causes these claims to be incomplete with respect to the essential final/recovered chromatographic product/fraction obtained thereby (see, e.g., MPEP 2172.01).

Applicant respectfully traverses.

As currently amended claims 1 and 8 now comprise the steps of: (a) “separating the filtrate into fractions” using “at least one” method of chromatographic separation; (b) identifying the fractions having chromatographic activity; and (c) using the fractions to produce an anti-neoplastic pharmaceutical composition. Thus, all claims both independent and dependent comprise the step of chromatographic separation. Moreover, Applicant asserts that all pending claims now clearly state what constitutes the final pharmaceutical product. Accordingly, Applicant believes that the rejection of the claims under 35 U.S.C. §112, second paragraph, has been overcome and may now properly be withdrawn.

IV. Rejection under 35 U.S.C. §102/103

A. Claims 1 and 7 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Ojukwu *et al.* (*Bull. Anim. Health Prod. Afr.*, 1982 —Vetu Abstract) or over Almagboul *et al.* (*Fitoterapia*, LIX:393-396, 1988), or over Obatomi *et al.* (*Phytotherapy Res.* 11:171-173, 1997). Specifically, the rejection asserts

A water extract obtained from the leaves of *Vernonia amygdalina* is apparently claimed.

Each of the cited references disclose a water extract obtained from the leaves of *Vernonia amygdalina* and, thus, appear to be identical to the presently claimed product... The reference water extracts would inherently comprise a peptide of claim 7 since the claimed peptides(s) would be naturally present within *Vernonia amygdalina* leaves as well as inherently water soluble.

In the alternative, even if the claimed filtered aqueous plant extract product is not identical to the referenced aqueous plant extracts with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced aqueous plant extracts are each likely to inherently possess the same

characteristics of the claimed aqueous plant extract particularly in view of the similar characteristics which they have been shown to share including being water extracts obtained from the leaves thereof (e.g., if not expressly taught, a filtered vs. a non-filtered extract are not deemed to provide patentable distinction to the claimed invention because their bioactivities would not be reasonably expected to differ, and, further, it would be atypical in the herbal art not to remove the extraneous plant material from the final extract product via one of various conventional means including filtration—such other removal means being essentially equivalent to removal via conventional filtration). Thus the claimed invention would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. 103.

Applicant respectfully traverses.

The standard for anticipation under 35 U.S.C. §102 is set out in Chapter 2100 of the MPEP, which recites, *inter alia*, that:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a singly prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

See MPEP §2131. Applicant asserts that none of the cited references anticipate the currently pending claims under this standard. None of the cited references teach, either expressly or inherently, separating an aqueous *Vernonia amygdalina* extract by a chromatographic method and identifying fractions having anti-neoplastic activity as required by all currently pending claims. Accordingly each of the cited references fail the test for anticipation as set out in MPEP §2131. Therefore, Applicant believes that the rejection of claims 1, and 7 under 35 U.S.C. §102(b) has been overcome and may now properly be withdrawn.

The criteria that must be met to establish a *prima facie* showing of obviousness are set out in Chapter 700 of the MPEP, which recites in pertinent part that:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must

be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

See, MPEP 706.02(j).

Applicant asserts that the cited references fail to meet any, let alone all, of the criteria that must be met to render the current claims obvious. There is nothing in any of the cited references that provides a motive or suggestion to modify the teachings of those references so as to provide a composition or method comprising preparing chromatographic fractions of an aqueous extraction of *Vernonia amygdalina* in order to provide a pharmaceutical composition with anti-neoplastic activity. Thus, the first criteria cited above is not met.

Similarly, the cited art references fail the second requirement in that they provide no teaching that would give one of ordinary skill in the art a "reasonable expectation" that a anti-neoplastic pharmaceutical composition could be prepared as claimed.

Finally, the cited art does not teach or suggest all of the claim limitations. There is nothing in the cited art that suggests that a anti-neoplastic pharmaceutical composition might be prepared from the leaves *Vernonia Amygdalina* plants.

Thus, the cited references clearly fail to meet any of the requirements set out in MPEP §706 as being required to establish a *prima facie* case of obviousness. Accordingly, Applicant asserts that this rejection has been overcome and may now properly be withdrawn.

B. Claims 1, 7, and 8 are rejected under 35 U.S.C. §103 as allegedly being unpatentable over Ojukwu *et al.*, Almagboul *et al.*, and Obatomi *et al.* The rejection specifically states:

Each of the cited references teach a water extract obtained from the leaves of *Vernonia amygdalina* (see entire documents). The reference water extracts would intrinsically comprise a peptide of claim 7 since the claimed peptide(s) would be naturally present in *Vernonia amygdalina* leaves as well as intrinsically water-

soluble. The adjustment of conventional working conditions (e.g., soaking the leaves in water then crushing vs. crushing then soaking, filtering the water extract to remove extraneous leaf material therefrom) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant respectfully traverses.

As described in part "A.", *supra*, there is nothing in the individual art cited which teaches or suggests the instantly claimed invention. Moreover, Applicant argues that there is nothing in the combination of the cited art which renders the currently pending claims obvious. That is, there is nothing in the combination of the cited art which teaches or suggest that the cited art might be modified so as to provide the currently claimed anti-neoplastic pharmaceutical composition. Nor is there anything in the cited art that teaches or suggests the currently claimed method for preparing an anti-neoplastic pharmaceutical composition.

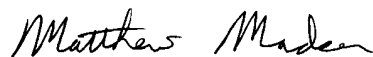
Thus, with respect to the amended claims, the combination of the cited art fails to meet any, let alone all, of the criteria set out in MPEP §706 as being required to establish a *prima facie* case of obviousness. Accordingly, Applicant believes that the rejection of claims 1, 7, and 8 under 35 U.S.C. §103(a) as being obvious over the cited art has been overcome and may now properly be withdrawn.

V. Conclusion

In view of the foregoing Amendments and Remarks, Applicant believes that all rejections of the currently pending claims have been overcome and that the case is now in condition for immediate allowance. Accordingly, Applicant respectfully requests favorable reconsideration of the application and issuance of a "Notice of Allowance" therefor.

The Examiner is invited to contact the undersigned patent agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: September 17, 2003